"Global Leaders in Technical and Engineering Consulting Services for cGMP Manufacturing Facilities, Laboratories & Support Infrastructure"

# Cleaning Validation (CV)

- Aligning cleaning validation with toxicological evaluation provides tools to meet regulatory expectations, implementing results in compliance, and patient safety.
- Modern cleaning programs focus on patient safety and must include health-based exposure limits (HBEL) considering identification of hazards and evaluation of the dose-response relationship.

Deliverables include:

- Customized solution for your CV Master Plan
  - Cleaning Process Design & Development
  - Cleaning Process Performance Qualification
  - Cleaning Process Verification
- Author/revise CV SOPs
- Evaluate toxicity of biopharmaceutics, therapeutic proteins, chemicals, and active pharmaceutical ingredients
  - Determine No Observed Adverse Effect Level (NOAEL)
  - Calculate Permitted Daily Exposure (PDE)
  - Determine Acceptance Criteria that take account of limits for the carryover of product residues with consideration to toxicological evaluation.

## Regulatory & Guidance Documents:

- FDA 1993, Validation of Cleaning Processes, Guide to Inspections Validation of Cleaning Processes
- EudraLex, Vol 4 GMP Guidelines, Annex 15
- European Medicines Agency: Guideline on setting Health
- Based Exposure Limits for Use in Risk Identification in the Manufacturer of Different Medicinal Products in Shared Facilities
- ICH Q3
- ISPE Baseline Guide Volume 7, Second Edition, Risk-based Manufacture of Pharmaceutical Products
- PDA TR 29, Points to Consider for Cleaning Validation
- PDA TR 49, Points to Consider for Biotechnology Cleaning Validation


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